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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,262	04/17/2002	Bruno Cricre	017751-030	8894

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,262	CRIERE ET AL.	
	Examiner	Art Unit	
	Lakshmi S Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13 were pending. New claims 14-20 have been added. Claims 1-20 are present in the application.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 103

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,5456,28 ('628) in view of U.S. Patent No. 6,074,670 ('670) or over '670 itself.

'628 teach pharmaceutical composition comprising effective amounts of fenofibrate and excipients and suspension stabilizers. Among the suspension stabilizers, '628 teach cellulose derivatives including hydroxypropylmethyl cellulose (HPMC) (col. 2, lines 44-53), and the excipients of '628 include one or more of polyglycolized glycerides such as Gelucire or poloxamer (col. 3, lines 1-35 and col. 4, lines 26-35), both of which read on the instant surfactant. '628 teach fenofibrate in the amount of 5% to 95%, preferably 45% to 55% (col. 3).

'670 teach immediate release fenofibrate composition comprising micronized fenofibrate, having a particle size of less than 20 microns or even less than 10 microns (col. 3, lines 65-67), excipients selected from sugars, starches or celluloses such as HPMC (col. 4) and surfactants including sodium lauryl sulfate poloxamer etc (col. 4). '670 teach a ratio of fenofibrate to hydrophilic polymer between 1/10 and 4/1 (col. 5) and teach up to 40% fenofibrate by weight of the composition. '670 further suggests the same process of preparing the composition i.e., spraying a suspension of micronized fenofibrate together with a hydrophilic polymer such as cellulose and a surfactant (col. 5, lines 30-35)

'628 do not teach micronized fenofibrate, claimed percentage of fenofibrate or the process of preparing fenofibrate as claimed. '628 also fail to teach the claimed viscosity of HPMC. '670 fail to teach fenofibrate above 60% and the claimed ratios and viscosities. However, the teaching of '670 is analogous to the instant invention in that '670 is also directed to increasing the bioavailability of fenofibrate, despite the art known formulations containing micronized fenofibrate, cellulose derivatives and surfactant. '670 suggest spraying a suspension of fenofibrate (micronized), polymer and a surfactant on an inert core (reads on instant inert granules) improves the bioavailability. Examiner notes that instant specification also is directed to increased bioavailability and is achieved by the same method as that of '670. While '670 teaches fenofibrate up to 40% and not at last 60% as claimed, '670 is in the same field of endeavor and solving the same problem of increased bioavailability of fenofibrate. Accordingly, absent evidence to the contrary optimizing the amount of fenofibrate in the composition of '670 with expectation to obtain the desired dissolution profile of fenofibrate would have been within he scope of a skilled artisan. Alternatively, it would have been obvious for a skilled artisan at the time of the instant invention to prepare a composition containing micronized fenofibrate employing the process of preparing the fenofibrate composition (ass taught by '670) in the teachings of '628 because, '670 teaches that the process enables a complete bioavailability of fenofibrate in a vary short period of time.

New claims 14-20 are rejected under this section on the same grounds mentioned in the preceeding paragraphs.

Response to Arguments

Applicant's arguments filed 5-5-04 have been fully considered but they are not persuasive.

Stamm ('670): Applicants argue that a prima-facie case of obviousness has not been established and that examiner merely identified elements of applicant's invention in cited publications. Applicants argue that Stamm pertains to a pharmaceutical composition containing 5 to 50% (preferably from 20 to 45% by weight, relative to the weight of the composition) micronized fenofibrate, a surfactant, and a hydrophilic polymer having increased solubility, thereby allowing increase bioavailability. Contrarily, applicants argue that the compositions of claims 1-20 require fenofibrate contents greater than or equal to 60% by weight, relative to the weight of the composition. Applicants argue that Stamm does not teach all limitations of claims 1-20 and may not be used on its own to establish a prima facie case of obviousness. Applicants argue that Stamm teaches hydrophilic polymers such as PVP, HPMC, hydroxymethylcellulose or hydroxypropyl cellulose, but prefers PVP as also seen in their example 1. Applicants also argue that example 1 of Stamm only contains 17% fenofibrate and thus requires two tablets in order to deliver 200 mg of fenofibrate (such as Lipanthyl 200M). Applicants' arguments are not persuasive because as agreed by applicants, Stamm teaches the claimed HPMC. Although Stamm prefers PVP, the prior art teachings are not limited to examples and instead should be considered as a whole. Applicant states that the instant invention overcomes the inefficiency of Stamm by involving low binder, thus resulting in a smaller size. However, instant claims only state HPMC and does not require the argued limitation of low binder or smaller size formulation.

Further, the prior art of record also recognizes the claimed HPMC as a binder and accordingly, optimization of the amounts by routine experimentation is within the scope of a skilled artisan, in the absence of any unexpected result. With respect to the argument that instant formulation provides at least the bioavailability of Lipanthyl 200M, instant claims do not recite the bioavailability parameters. Stamm teaches compositions containing the claimed active ingredient i.e., fenofibrate, binder-HPMC and surfactants of the instant invention. Accordingly, optimizing the amount of the active agent, fenofibrate, and polymers and binders and other excipient that aid in the release of fenofibrate (as taught by Stamm) would have been within the gambit of a skilled artisan.

Deboeck: Applicants argue that there is no suggestion or motivation to combine the teachings or to modify the teachings of Stamm and Deboeck because firstly, unlike Stamm, Deboeck permits a range of 5% to 95%; second, Deboeck fails to teach micronized fenofibrate; and third, Deboeck indicates a molten solution of non-micronized fenofibrate –polyglycolized glycerides, that is subsequently allowed to cool, wherein the cellulose derivative is added to the molten suspension as a stabilizer to avoid crystal formation. Applicants argue that given the contrasting nature of Stamm and Deboeck with respect to at least three components, one would not have been motivated to combine these two publications. Applicants' arguments have been considered but not found persuasive because instant claims are directed to a composition containing micronized fenofibrate, HPMC and a surfactant, with at least 60% of fenofibrate by weight of the total composition, and not the process of preparing the compostion. Accordingly, the question is whether the combination of the claimed components would have been obvious for one of an ordinary skill in the art at the time of the instant invention. Deboeck teaches fenofibrate

compositions containing high amounts (as high as 95%) of fenofibrate and suggests adding HPMC and surfactants such as poloxamer (see col. 2 and example in col. 4). However, Deboeck fails to teach micronized fenofibrate. The motivation to micronized fenofibrate in the teaching of Deboeck comes from the teachings of Stamm that micronization increases bioavailability. Applicants' argument that Stamm teaches maximum limit of fenofibrate to be 55% and hence actually teaches away from combination is not persuasive because, Stamm does not teach that fenofibrate cannot be used beyond 55% by weight of the composition. Applicants' argument that instant invention uses HPMC as a solubilizer as opposed to the teachings of Stamm and Deboeck is not persuasive because instant claims are directed to a product and product by process, but not a process per se. Further, claims do not recite the argued limitations of bioavailability. Both Stamm and Deboeck teach HPMC and accordingly it is expected to exhibit both functions i.e., solubilizer and stabilizer. Furthermore, both references teach bioavailability of fenofibrate formulations that are equal to or better than that of Lipanthyl 200M, a standard formulation also used for comparison in the instant specification. Therefore, it is examiner's position a prima facie case of obviousness has been established.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lakshmi S Channavajjala
Examiner
Art Unit 1615
September 10, 2004

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SUPERVISORY PATENT EXAMINER
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